Message

From: Walsh, Patrick [patrick-walsh@denka-pe.com]

Sent: 10/3/2019 8:20:00 PM

To: Vandenberg, John [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]

CC: Thayer, Kris [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=3ce4ae3f107749c6815f243260df98c3-Thayer, Kri]; Cascio, Wayne

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a1bd931ca2f84ea8ac2f4c44538f3589-Cascio, Wayne]; Jones, Samantha

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=eac77fe3b20c4667b8c534c90c15a830-Jones, Samantha]; Lavoie, Emma

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=86ac7844f12646c095e4e9093a941623-Lavoie, Emma]; Schlosser, Paul

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=121cf759d94e4f08afde0ceb646e711b-Schlosser, Paul]; Bahadori, Tina

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7da7967dcafb4c5bbc39c666fee31ec3-Bahadori, Tina]; Kirby, Kevin

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cbb65672f6f34545be460a66ff6fa969-Kirby, Kevin]

Subject: RE: Chloroprene PBPK: Peer review charge questions

Attachments: ATT00001.txt

Hi John,

I've spoken with the Ramboll team and they feel that a week is adequate time to prepare a response. So unless something changes, we will have it to you by close of business on Wednesday, 10/9/19.

Thanks again!



Patrick A. Walsh, CIH SHE Manager Denka Performance Elastomer LLC 560 Highway 44 LaPlace, LA 70068 Office: 985-536-7573 | Cell: 251-321-5989

patrick-walsh@denka-pe.com

From: Walsh, Patrick

Sent: Wednesday, October 2, 2019 5:51 PM

To: Vandenberg, John < Vandenberg. John@epa.gov>

Cc: Thayer, Kris <thayer.kris@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Jones, Samantha

<Jones.Samantha@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>;

Bahadori, Tina <Bahadori.Tina@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>

Subject: RE: Chloroprene PBPK: Peer review charge questions

Thanks, John. I'll forward to the Ramboll team. I'll first ask them to tell me if a week is enough time (don't want to make an assumption). If we need more, I'll let you know. This is a priority for all of us and we want to make sure we get it right. Thanks again for the opportunity.



Patrick A. Walsh, CIH SHE Manager Denka Performance Elastomer LLC 560 Highway 44 LaPlace, LA 70068 Office: 985-536-7573 | Cell: 251-321-5989 patrick-walsh@denka-pe.com

From: Vandenberg, John < Vandenberg_John@epa.gov>

Sent: Wednesday, October 2, 2019 3:46 PM

To: Walsh, Patrick <patrick-walsh@denka-pe.com>

Cc: Thayer, Kris < thayer.kris@epa.gov>; Cascio, Wayne < Cascio.Wayne@epa.gov>; Jones, Samantha

<Jones.Samantha@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>;

Bahadori, Tina <Bahadori. Tina@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>

Subject: Chloroprene PBPK: Peer review charge questions

Importance: High

Patrick,

We've been diligently evaluating the Ramboll report and conducting analyses related to physiologically-based pharmacokinetic parameters and modeling of chloroprene (references below).

We are moving forward to arrange through a contractor an independent letter peer review by appropriate experts.

In addition to the Ramboll report, we are providing an EPA analysis that we wish to have peer reviewed.

Per our discussion early this summer, we are providing for your information the attached draft Charge questions that will be addressed by the peer reviewers, plus an EPA analysis that we have developed.

Please let us know within a week (by next Wednesday) if you have any major comments on the Charge questions. We are not seeking any comments on the EPA analysis.

Thank you,

John

John Vandenberg, PhD
Director, Health and Environmental Effects Assessment Division
Center for Public Health and Environmental Assessment/ORD
U.S. Environmental Protection Agency/B243-01
Research Triangle Park, NC 27711
(919) 541-4527

References:

Ramboll. (2019). Incorporation of in vitro metabolism data in a physiologically based pharmacokinetic (PBPK) model for chloroprene.

U.S. EPA. (2019). In Vitro to In Vivo Extrapolation (IVIVE) of Metabolism and Non-Enzymatic Conjugation of (1-chloroethenyl) oxirane (1-CEO) and Estimation of Total 1-CEO Clearance in the Liver and Lung of Mice, Rats, and Humans.